



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,103	10/14/2005	Andrei Bugrim		5310

7590 04/08/2009
ANDREI BUGRIM
1011 PEARL STREET
ST. JOSEPH, MI 49085

EXAMINER

SKOWRONEK, KARLHEINZ R

ART UNIT	PAPER NUMBER
----------	--------------

1631

MAIL DATE	DELIVERY MODE
-----------	---------------

04/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,103	Applicant(s) BUGRIM ET AL.	
	Examiner KARLHEINZ R. SKOWRONEK	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 January 2009 has been entered.

Claim Status

Claims 1, 3, and 5-11 are pending.

Claims 2, 4, and 12 are cancelled.

Claims 1, 3, and 5-11 have been examined.

Claims 1, 3, and 5-11 are rejected.

Priority

This application was filed on 14 October 2005 under 35 USC 371 as the national stage of PCT/US03/19325, which was filed on 18 June 2003 and claims the priority of US provisional Application No. 60/389474, which was filed on 18 June 2002.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 21 January 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Declaration under 37 CFR 1.132

The declaration under 37 CFR 1.132 filed 21 January 2009 is insufficient to overcome the rejection of claims 1, 3, and 5-11 based upon Nakao et al. in view of Karp in view of Kuffner et al. applied under 35 USC 103(a) as set forth in the last Office action because: The declaration filed 21 January 2009 sets forth 2 main arguments. The first is directed to the summary of available resources for metabolic pathway reconstruction (paragraph 4 and 5). In paragraph 4, declarant argues the work of others was *“unable to fully satisfy the needs of the scientific community in terms of reconstructing comprehensive organism- and condition-specific pathways and providing adequate tools for the functional analysis of high-throughput molecular profiles”*. Declarant specifically points to 4 principle shortcomings of the art: (A) Lack of organism specificity; (B) Lack of comprehensive coverage; (C) Inability to integrate heterogeneous information on metabolism and cell signaling with clinical and other phenotypic data; and (D) Inability to combine pathways with high-throughput molecular data. The argument is not persuasive. Regarding declarant’s assertion in (D) (paragraph 4, p. 8), declarant has not provided objective evidence to support the assertion. Further, the cited art shows the integration of high throughput data with pathway reconstruction (Nakao et al.). Regarding declarant assertion in (C)(para. 4, p. 8), it is unclear what applicant means by heterogenous information. However, the cited art shows the integration of genomic data, metabolic information, and expression data (Nakao et al.) which are heterogenous information that include metabolic data, cell signaling and phenotypic data. Declarant has not provided objective evidence to the

Art Unit: 1631

contrary. Regarding declarant's assertions in (A) and (B), declarant has not provided objective evidence to support the assertions. In paragraph 5, p. 8, declarant argues the failure of others, asserting,

"...there have been multiple attempts by GeneGo's competitors to develop commercial tools that would allow analysis of high-throughput molecular data in the context of biological pathways and reconstruction of disease pathways...None of these attempts have resulted in commercially successful products, and many of these companies have ceased to exist as independent entities."

The argument is not persuasive. Paragraph 5 lists several companies and mergers, but does not indicate the commercial products offered by those companies which declarant views as having tried and failed to perform the claimed method. Declarant has not provided objective evidence that other have tried and failed to perform the claimed method.

The second argument is directed to commercial success. Paragraph 7 states, *"GeneGo, Inc. has successfully developed and marketed its flagship product, the MetaCore™ pathway analysis software, based on the presently claimed invention. Subsequently, additional products and services were developed and marketed that also utilize elements of the claimed invention"*. This is ineffective to overcome the rejection of record under 35 USC 103 (a) because the features responsible for the commercial success are not commensurate in scope with the claim invention (In re Tiffin, 448 F.2d 791, 171 USPQ 294 (CCPA 1971); Joy Technologies Inc. v. Manbeck, 751 F. Supp. 225, 229, 17 USPQ2d 1257, 1260 (D.D.C. 1990), aff 'd, 959 F.2d 226, 228, 22 USPQ2d 1153, 1156 (Fed. Cir. 1992)). The argument provides no evidence that the product or process which has been sold corresponds to the claimed invention, or that whatever

Art Unit: 1631

commercial success may have occurred is attributable to the product or process defined by the claims (Ex parte Standish, 10 USPQ2d 1454, 1458 (Bd. Pat. App. & Inter. 1988)). Paragraph 7 offers gross sales figures on the order of \$14,000,000 (line 4-5). However, these number are ineffective to overcome the rejection because no evidence of the market share (Cable Electric Products, Inc. v. Genmark, Inc., 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985)), or as to the time period during which the product was sold, or as to what sales would normally be expected in the market, Ex parte Standish, 10 USPQ2d 1454 (Bd. Pat. App. & Inter. 1988) is offered. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, and 5-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 3, and 5-11 are directed to processes for reconstructing the metabolism of a mammalian organism. The following analysis is taken from the guidance provided in the MPEP at 2104.IV, "Determine Whether the Claimed Invention Complies with 35 USC101". The claims are directed to processes. Here the claims are directed to the abstract idea of structuring data to create a reconstruction of the metabolism of a mammalian organism. The processes do not recite a physical transformation of matter from one state to another. Giving the claims

Art Unit: 1631

the broadest reasonable interpretation, the claims read on mental steps. In *Comiskey* (*In re Comiskey*, 84 USPQ2d 1670) the court established that “the application of human intelligence to the solution of practical problems is not and of itself patentable” (at 1680). In *Comiskey*, the court stated explicitly “mental processes - or processes of human thinking - standing alone are not patentable even if they have a practical application” (at 1679). The court in *Comiskey* stated, “Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone and untied to another category of statutory subject matter even when a practical application was claimed” (at 1680). The court’s recent decision in *In re Bilski* confirmed, “a process is patent-eligible under 35 USC 101 if it is tied to a particular machine or apparatus or if it transforms a particular article into a different state or thing” (*In re Bilski*, 88 USPQ at 1391, 2008). In the instant claims, the process is not tied to a class of statutory invention. Output is insignificant post-solution activity and does not represent a significant tie to another category of invention. The court in *Comiskey*, stated “the court rejected the notion that mere recitation of a practical application of an abstract idea makes it patentable, concluding that ‘[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula’” citing *Flook* (437 U.S. at 586, 590). The recent decision in *Bilski* confirmed the court’s position regarding insignificant pre- or post-solution activity (i.e. insignificant extra-solution activity) as stated in *Comiskey* (see *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008) at p. 13-96-1397). Applicant is encouraged to consider the recent BPAI informative decisions *Exparte Langemyr* (No.

Art Unit: 1631

2008-1495 (28 May 2008)) and *Exparte Biliski* (No. 2002-2257 (26 September 2006)) for further clarification of the above grounds of rejection.

Claim Rejections - 35 USC § 112

Response to Arguments

The rejection of claim 12 is withdrawn in view of its cancellation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1631

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following rejection is necessitated by amendment of the claims.

Claims 1, 3-5, and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [<http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html>]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000).

The claims are directed to a method for reconstruction of the metabolism of an organism in which data regarding the organism metabolism is collected; linked to metabolic pathways; interconnections between metabolic pathways are identified; and a map of the organism's metabolism is created.

Nakao et al. shows a method of metabolism reconstruction. Nakao et al. shows that data regarding the organism's metabolism is collected (sect 3.1). Nakao et al. shows that the data is linked to metabolic pathways and inter connections are identified to create a map of the organism's metabolism (figure 4). Nakao et al. shows that the metabolic reconstruction also comprises data regarding metabolism of an organism for both a reference (non-diseased) and perturbed (diseased) state (p. 95). Nakao et al. refers to reference and perturbed states, and the KEGG database actually contains data related to diseased and non-diseased states in humans (see the KEGG database table

of contents from February 1999) Nakao et al. shows that pathway maps can be reconstructed for eukaryotes such as fruit fly, mouse, human and *Saccharomyces cerevisiae*.

Nakao et al. does not show the identification of drug targets.

Karp et al. shows that drug targets can be identified through the analysis of pathway genome databases (p. 278, col. 2 to p. 279, col. 1). Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery (abstract).

Kuffner et al. shows a method of that combines the information found on various metabolic databases to produce a differential metabolic display (DMD). The DMD of Kuffner et al. allows the comparison between disease pathways and non-disease pathways (p. 825, col. 2 –p. 825, col. 1). Kuffner et al. suggests differences can be identified from the comparison. Kuffner et al. shows that the data to generate DMD's are taken from such databases as KEGG (p. 826, col. 1). Kuffner et al. shows the type of data obtained from the databases comprises biochemical units further comprising metabolic steps (enzymes), chemical compounds (ligands, cofactors, substrates, and products), reactions, and enzymatic function (genes and proteins) (p. 826, col. 2 and figs 1 and 5). Kuffner et al. shows an annotation table comprising fields such as sub cellular localization and intracellular compartmentalization (figure 5). Kuffner et al. suggests that DMD will be useful for target identification (abstract). Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of

Art Unit: 1631

unknown function and to propose the existence and/or absence of specific proteins or protein functions (p. 834, col. 2).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of reconstructing an organism's metabolism of Nakao et al. with the drug target identification of Karp et al. because Karp et al. shows that that integrated genome-metabolic pathways provide a framework for improved drug discovery. It would have been further obvious to modify the method of reconstructing metabolism with collected data of Nakao and the use of pathways to identify targets of Karp et al. with the DMD's of Kuffner et al. because Kuffner et al. shows DMD's allow the display of significant differences, to identify gaps in specific pathways and enable the interpretation of expression data by making predictions for proteins of unknown function and to propose the existence and/or absence of specific proteins or protein functions.

Response to Arguments

Applicant's arguments filed 21 January 2009 have been fully considered but they are not persuasive. Applicant argues that the teaching of Nakao has been mischaracterized by conflating two different components of the KEGG system. The argument is not persuasive. Nakao et al. states explicitly in the abstract:

"The massively parallel hybridization technologies by DNA chips and microarrays make it possible to monitor expression patterns of the whole set of genes in a genome under various conditions. The vast amount of data generated by such technologies necessitates the development of a new database management system that integrates expression data with other molecular biology databases and various analysis tools. We report here an extension of our KEGG (Kyoto Encyclopedia of Genes and Genomes) and DBGET/LinkDB systems for analyzing gene expression data in conjunction with pathway information and genomic information. It

Art Unit: 1631

is now possible to make use of expression data for the reconstruction of pathways from the complete genome sequences.”

Thus, Nakao et al. is directed to combining the different components of the KEGG system. Applicant argues that Nakao et al. do not suggest reconstruction of human metabolism. The argument is not persuasive. First, Nakao et al., in the abstract, states, “It is now possible to make use of expression data for the reconstruction of pathways from the complete genome sequences.” Second, Nakao et al. suggests, “To effectively analyze the new type of data derived from the expression profiles we should integrate them with the functional data such as pathways and assemblies, as well as with the traditional molecular biology data such as nucleotide and amino acid sequences” (p. 94, para 1, line 3-5). Third, Nakao et al. states, “One of the main features of KEGG is a collection of pathway maps, which computerizes the network information of molecular interactions such as for metabolism and signal transduction. Another feature of KEGG is a collection of genome maps for completely sequenced organisms, as well as for the fruit fly, **mouse, and human**” (p. 94, para.2, line 6-9). Emphasis added. Bridging pages 94 and 95, Nakao et al. shows, “In this paper, we report an integration of gene expression data into the DBGET/LinkDB and KEGG systems and show how we can make use of the integrated system for analysis of expression data. The integration includes a visualization of genome-scale gene expression data not only by the standard array view but also by the genome map and pathway map views. The analysis includes a metabolic pathway reconstruction by differential gene expression patterns obtained by comparison of the reference state and the perturbed state (e.g. the wild-type and a disruptant, or the control and an environmental shift)” (p. 94, para 3, line 1-3 to p. 95,

Art Unit: 1631

line 1-4). Taking the totality of the teachings, Nakao et al. at least suggests the reconstruction of mammalian pathways. Applicant argues that Nakao et al. does not suggest using high throughput screening information. The argument is not persuasive. Nakao et al. shows the use of high throughput data in reconstructing metabolic pathways (abstract, p. 94, p. 95, and p.99). Applicant argues that Nakao et al. only shows the reconstruction of microbial pathways and asserts the KEGG database did not have mammalian specific pathways. The argument is not persuasive for the reasons above. It is unclear what applicant is arguing with respect to Karp et al. Karp is cited for the teaching that drug targets can be identified by analyzing pathway genome databases such as KEGG. Similarly it is unclear what applicant is arguing with regards to Kuffner et al. Kuffner was cited for the comparison of diseased pathway to non-diseased pathway. Applicant's argument that a specific disease was not identified in Kuffner is not persuasive or applicable because the claim is not limited to a specific disease. Regarding applicants argument that Kuffner is not an enabling reference, the argument is interpreted to be directed to the expectation of success. The argument is not persuasive because one of ordinary skill in the art would have had a reasonable expectation of success of applying the method of Kuffner et al. to the pathway reconstruction of Nakao et al. because Kuffner, Nakao, and Karp all show the construction of metabolic pathways. The rejection is maintained.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource,

Art Unit: 1631

[<http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html>]], in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000) as applied to claims 1 and 3-5 above, and further in view of Okubo et al. (Nature Genetics, Vol. 2, p. 173-179, November 1992) .

Claim 6 is directed to data that is Expressed sequence tag (EST) data.

Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above teach a method of metabolic reconstruction.

Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above do not show EST data.

Okubo et al. shows expression data that comprises EST data can be used in mapping (p. 178, col. 1). Okubo shows the advantage of using expressed sequence tags results from a comparison of data from the same cells under different physiological conditions that will aid in the understanding of cell- and time-dependent control of gene expression (p. 176-177, col. 2). Okubo et al. shows that maps of expressed genes will help in the search for biologically and industrially interesting genes (p. 173, col. 1).

It would have been obvious to one of skill in the art at the time of invention to modify the method of metabolism reconstruction of Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above with the incorporation of EST data of Okubo et al. because Okubo et al. shows that a map of expressed genes will facilitate the search for biologically and industrially interesting genes.

Response to Arguments

Applicant's arguments filed 21 January 2009 have been fully considered but they are not persuasive. Applicant's arguments are not persuasive for the reasons above. The rejection is maintained.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakao et al. as supported by the KEGG table of contents as of February 1999(online resource, [<http://web.archive.org/web/19990203053246/www.genome.ad.jp/kegg/kegg2.html>]), in view of Karp et al. and in view of Kuffner et al. (Bioinformatics, Vol. 16, No. 9, p 825-836, 2000) as applied to claims 1 and 3-5 above, and further in view of Kumar (Reactive and Functional Polymers, Vol. 46, p. 1-27, 2000) in view of Tile D4 of the Boehringer Biochemical pathways map (Roche Applied Science, 1993 Online [http://www.expasy.org/cgi-bin/show_image?D4&up]).

Claim 11 is directed to the at least one pathway comprising a chitinase.

Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above teach a method of metabolic reconstruction.

Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above do not explicitly show a pathway comprising a chitinase.

Tile D4 of the Boehringer Biochemical pathways chart shows a biochemical pathway that comprises a chitinase. Tile D4 shows that chitin is degraded by a chitinase to produce chitobiose which is in turn degraded by N-Acetyl-beta-Glucosamidase to produce N-Acetyl-D-Glucosamine. The blue lines as indicated by the legend denote biochemical reactions that occur in animals (p. 4).

Kumar shows that chitin is a functional material of high potential. Kumar shows that the immunogenicity of chitin is exceptionally low (p. 1, col. 1). Kumar shows that chitin is used to dress wounds and as artificial skin (p. 9, col. 2). Kumar shows that wound healing is accelerated by the degradation of the chitin derivative, chitosan (p. 10 col. 1-2).

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of metabolism reconstruction of Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above with a pathway comprising a chitinase as in the tile D4 because Kumar shows the wide range of beneficial applications of chitin. It would have been further obvious to modify the metabolic pathway reconstructions of Nakao et al. in view of Karp and in view of Kuffner et al. as applied to claims 1 and 3-5 above with a pathway comprising tile D4 because the substitution of a metabolic pathway reconstructed to comprise a chitinase for another pathway would have yielded predictable results.

Response to Arguments

Applicant's arguments filed 21 January 2009 have been fully considered but they are not persuasive. Applicant's arguments are not persuasive for the reasons above. The rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

Art Unit: 1631

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This rejection is reiterated from the previous Office Action.

Claims 3, 7 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4 of copending Application No. 11/499, 437. Although the conflicting claims are not identical, they are not patentably distinct from each other because Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 are directed to the same use, namely to identify drug targets. Claim 1 of Application no. 11/499,437 is alternatively directed to identifying gene therapy targets. Both claim 3 of the instant application and claim 1 of Application No. 11/499, 437 perform the same steps and produce the same result. In addition, claims 7 and 8 of the instant application are directed to further limitation of the data specifically chemical compounds, reading on metabolite of as recited in claim 4 of Application No. 11/499, 437, and proteins, also as recited in claim 4 of Application No. 11/499, 437.

Art Unit: 1631

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone number is (571)272-9047. The examiner can normally be reached on 8:00am-5:00pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. R. S./
Examiner, Art Unit 1631

8 April 2009

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631